Remarks

Claims 1-61 are pending.

Rejections under 35 USC § 103

Curtet and Duclos or Curtet and Ikeda.

Claims 1-61 stand rejected under 35 USC § 103 as being obvious over Curtet (US Patent No. 4,895,726) in view of Duclos (US Patent 5,776,495) or Ikeda (US Patent 5,952,356).

Applicants respectfully traverse the rejection.

The claimed invention provides a suspension of an active ingredient, which is an intermediate product which is used in the manufacture of a final composition which exhibits superior results. *See* Specification at page 7, lines 19-21. The suspension, when used in a fluidized bed granulator, provides a final composition having an improved dissolution. The suspension itself is not used as a dosage form for the active ingredient, but as an intermediate in the manufacture of the final dosage form. Again, the claimed invention is dedicated to a product that it not used as a pharmaceutical composition for administration to a patient in need thereof, but to an intermediate product.

Curtet does not disclose or suggest the claimed suspensions. This is again acknowledged by the Examiner in the office action at page 4, first full paragraph:

> *"Curtet et al. do not expressly state a fenofibrate suspension, but rather a composition, wherein co-micronized granules are contained in the presence of water."*

The Examiner further states that:

> *"However, it is well known in the art to incorporate a medicament, such as fenofibrate in combination with water and a surfactant to form a suspension."*

As discussed above, the suspensions of the invention are not directly administered to a patient, but are an intermediate product in the manufacture of a final composition. The fact that suspensions are known galenic formulations is irrelevant to the claimed invention.

The PTO contends that it is obvious for the skilled person to modify a solid composition into a liquid, aqueous, suspension. The PTO has indicated in the "Response to Arguments" section that:

> *"The prior art initially recognizes and teaches a similar formulation as claimed, which utilizes the same components as that being claimed by the Applicant."*

Applicant respectfully disagrees. The prior art, i.e. Curtet, only discloses solid dosage forms. *See* abstract and claim 1 of Curtet. It is not disputed that a suspension is a liquid formulation. Thus, it cannot be said that Curtet teaches a "*similar*" formulation as claimed, because a solid is not "*similar*" to a liquid.

The question is whether the skilled person would have modified Curtet, i.e. would have achieved a liquid suspension as is claimed. Duclos and Ikeda do not provide the necessary motivation.

Duclos is relied upon for its teaching an adjunction of non-ionic surfactants, solubilizing agents and micronization. Micronization and surfactants are already present in Curtet, so the only element Duclos would disclose and that would not already be part of Curtet is the use of solubilizing agents. However, this statement is found only in the introductory part of Duclos and is not disclosed elsewhere. Duclos' teaching of solubilizing agents is thus defective. Thus, Duclos cannot fill in the gap between the solid dosage form of Curtet and the liquid suspension of the invention. In any event, Duclos fails to teach a liquid suspension as is – indirectly - acknowledged by the Examiner at page 4, second full paragraph.

Ikeda is relied upon for its teaching of suspensions. It is not disputed that suspensions are known galenic formulations. The skilled person would not consider liquid suspensions given the teachings in Curtet. Applicants respectfully submit that Curtet teaches away from a suspension. Indeed, Curtet states (e.g., abstract and claim 1):

> *"a composition containing a co-micronized mixture of particles of fenofibrate and a solid surfactant"* (emphasis added).

Thus, Curtet requires the surfactant to be in a solid form. The claimed invention requires the surfactant or the polymer to be in a solution, hence, in a dissolved form, which is very different from a solid form. Accordingly, Curtet cannot render the claimed invention obvious.

Curtet requires that the fenofibrate and the solid surfactant be co-micronized. The skilled person would not manufacture a suspension of fenofibrate in a solution comprising a surfactant. The skilled person would expect to have the fenofibrate in the suspended state and the surfactant in a dissolved state, thus in separate phases. The skilled person would thus expect to lose the benefits described in Curtet i.e. having both components co-present (in the same, solid, phase). The skilled person would not prepare a suspension where the fenofibrate would no longer be together with the surfactant in the same state (solid, co-micronized). Dissolution of surfactant in a solution would cause the surfactant to lose its micronized state. This is opposite what is required in Curtet (column 1, lines 52-53):

> *"The surfactant will be selected from solid surfactants so that is can be co-micronized with the fenofibrate."*

and paragraph bridging columns 4 and 5

> *"[...]a method for improving the bioavailability of fenofibrate in vivo is recommended, the said method comprising co-micronization of the fenofibrate and a solid surfactant, the said co-micronization being carried out by micronization of a fenofibrate/solid surfactant mixture until the particle size of the powder obtained is less than 15μm [...]"*

Curtet requires a solid surfactant and a powder, and thus a solid dosage form. By changing from a solid into a liquid composition, the principle of operation of Curtet would be changed. However, as is recalled in MPEP at 2143.02, "*the proposed modification cannot change the principle of operation of a reference*".

In view thereof, Applicants respectfully submit that the presently claimed invention is unobvious over Curtet in view of Duclos or Ikeda, and respectfully request that the rejection under 35 USC § 103 be withdrawn.

Conclusion

An early and favorable reconsideration and allowance of claims 1-61 is respectfully requested. Examiner Sheikh is encouraged to contact the undersigned to expedite prosecution of this application.

Respectfully submitted,

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